

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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**IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESAL PRICE LITIGATION**

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**THIS DOCUMENT RELATES TO:**

*State of California, ex rel. Ven-A-Care of the Florida  
Keys, Inc. v. Abbott Laboratories, Inc., et al.*  
Case No: 1:03-cv-11226-PBS

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) **MDL No. 1456**  
) **Master File No. 01-12257-PBS**  
) **Subcategory Case No. 06-11337**  
)  
) **Judge Patti B. Saris**  
)  
) **Magistrate Judge**  
) **Marianne B. Bowler**  
)  
)

**PLAINTIFFS' BRIEF IN OPPOSITION TO DEY'S  
MOTION FOR PARTIAL SUMMARY JUDGMENT**

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## PRELIMINARY STATEMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 56.1, Plaintiffs, the State of California and Ven-A-Care of the Florida Keys, Inc. (“Plaintiffs”), submit this Memorandum in Opposition to Dey, Inc. And Dey, L.P.’s (“Dey’s”) Motion for Partial Summary Judgment (the “Motion”). Plaintiffs incorporate by reference their Memorandum in Opposition to Defendants’ Joint Motion for Summary Judgment, their Response to Defendants’ Joint Statement of Undisputed Material Facts, their Response to Dey’s Statement of Undisputed Material Facts in Support of Dey’s Motion for Partial Summary Judgment, and their Statement of Additional Undisputed Material Facts in Opposition to Dey’s Motion for Partial Summary Judgment. For the reasons set forth in those documents and further discussed below, Dey’s Motion should be denied.

In this action, Plaintiffs allege that Dey systematically defrauded California’s Medicaid program, known as Medi-Cal, by reporting grossly inflated Average Wholesale Prices (“AWPs”) for certain Dey drugs to First DataBank (“FDB”), the pricing publisher that California used in calculating reimbursement for providers who dispensed Dey’s products to Medi-Cal beneficiaries. By knowingly submitting grossly inflated AWPs to FDB, Dey caused Medi-Cal to pay far more for its drugs than Medi-Cal should have paid under the governing regulations, unlawfully causing millions of dollars in Medi-Cal overpayments. Plaintiffs seek to recover appropriate damages and penalties under California’s False Claims Act (“CA FCA”), CAL GOV’T CODE § 12650 *et seq.*<sup>1</sup>

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<sup>1</sup>

(a) Any person who commits any of the following acts shall be liable to the state or to the political subdivision for three times the amount of damages which the state or the political subdivision sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state or political subdivision for a civil penalty of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000) for each false claim:

Dey moves for partial summary judgment on two grounds. First, Dey argues that Plaintiffs claims are barred under a purported “government knowledge” defense because California was allegedly aware of Dey’s grossly inflated AWP’s and therefore allegedly cannot prove the elements of falsity, scienter, and causation as to all claims that accrued after January 1999. (Dey SJ Br. 2-9.) Second, Dey argues that California has not shown that it sustained any damages on certain drugs. (Dey SJ Br. 9-11.)

As to the first argument, Dey’s government knowledge contentions are meritless on both factual and legal grounds, as set forth below.

As to Dey’s second issue, Plaintiffs agree that Medi-Cal did not incur *damages* as to 37 of the 65 NDCs which are named in California’s First Amended Complaint, but are not addressed in the expert report of Plaintiffs’ damages expert, Dr. Jeffrey J. Leitzinger. (Plaintiffs previously advised Dey they were not pursuing claims as to certain products referenced in the Complaint.) More specifically, Plaintiffs have dropped their damages claims as to NDCs in which calculated overpayments fall at or under a 25 per cent margin (or “speed bump”) over the estimated acquisition cost computed by Dr. Leitzinger.

Plaintiffs are pursuing damages on five Dey drugs, which were labeled and sold under twenty-eight National Drug Codes (“NDCs”).<sup>2</sup> Dr. Leitzinger computed damages for those NDCs based on an analysis of Dey’s own business records, after taking into account the chargebacks, rebates, and other discounts Dey disregarded when it reported its AWP’s. In other

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(1) Knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval.

(2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision.

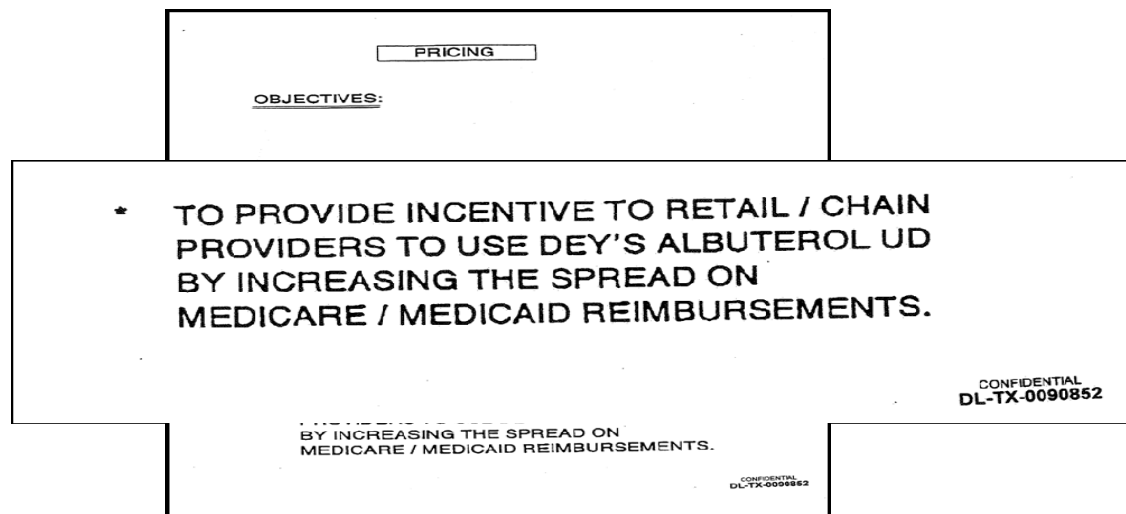
CAL GOV’T CODE § 12651(a).

<sup>2</sup> Those drugs are Acetylcysteine, Albuterol, cromolyn nebulizer solution, ipratropium bromide, and metaproterenol.

words, even though, damages are *not* an essential element of an FCA claim,<sup>3</sup> Plaintiffs have limited their case for damages to 28 NDCs, as to which Dey's false price reporting caused substantial overpayments by Medi-Cal during the eleven year time period from January 1994 through December 2004.

### FACTUAL OVERVIEW

Dey admits that it set and reported AWP's for its products without regard to actual wholesale prices, average or otherwise. Moreover, the evidence shows that Dey did so knowingly, in order to maximize the sales of its products at Medi-Cal's expense. As early as 1992, Dey's senior executives developed a strategy to sell albuterol by marketing the spread between reported AWP's and actual sales prices—at the expense of Medi-Cal and other government programs that based their payments of Dey's reported prices. Dey's objectives are revealed in a 1992 memo that the company's Vice President Robert Mozak sent to CEO Charles Rice, President Jean-Pierre Termier, and CFO Pam Marrs:



<sup>3</sup> Damages are not a necessary element of the State's claims under the CA FCA. CAL. GOV'T CODE § 12651(a); *see State v. Altus Finance, S.A.*, 36 Cal. 4th 1284, 1299 (2005); *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 445-46 (6th Cir. 2005).

Dey's understanding is apparent from its stated pricing strategy: "increase the spread ...by lowering acquisition cost *more than AWP*." (CA Resp. Dey SOF ¶ 8.) Dey did not attempt to report AWP's that were a good faith estimate of actual average wholesale prices. Rather, it manipulated those AWP's to increase the spreads on its drugs, and thereby sell more of its products at the expense of Medi-Cal. As the memo described above makes clear, there is no dispute over the fact that Dey was aware that its inflated AWP's would help it sell its products, by providing excess profits to providers at the expense of the government.

Dey does not contest the fact that it reported AWP's that had no definable or reasonable relation to actual wholesale prices. Dey instead claims that it was entitled to ignore the requirements of the statutes and regulations that governed Medi-Cal's reimbursement system, on the grounds that its practice was to set AWP's at approximately 10% below the comparable brand. In making that argument, Dey ignores the fact that it actually raised AWP's for certain products when to do so was to its advantage—but almost never lowered its AWP's, even as the actual wholesale prices of its drugs plummeted in response to competition. Plaintiffs consequently dispute Dey's assertion that once an AWP was set, it was never changed. CEO Charles Rice admitted that Dey changed the AWP on Euthyrox in order to meet the competition. (CA Resp. Dey SOF ¶ 12.) Indeed, Dey adjusted the AWP's for nineteen other products at the same time. (CA Resp. Dey SOF ¶ 12). In other words, Dey's asserted practice of never changing its AWP's was conveniently disregarded when Dey perceived a competitive advantage to do so.

Dey further defends its false price reporting by arguing that, beginning in 1999, it notified Medi-Cal that its AWP's did not represent actual wholesale prices. But Dey *never* advised Medi-Cal that it routinely set its AWP's at approximately 10% off the brand AWP and left them at that

level regardless of declining actual acquisition prices, and never revealed the huge spreads between its real prices and its reported AWP. For this reason alone, there are triable issues of material fact as to whether California was fully apprised of Dey's conduct and, if so, whether California acquiesced in that conduct by continuing to use Dey's AWP in Medi-Cal's reimbursement program. Moreover, it is noteworthy that Dey sent these purported "AWP disclaimers" only after it knew it was under investigation. Dey's CEO Charles Rice admitted that Dey received a Department of Justice subpoena in 1997, and that Dey began sending the price notification letters in 1999 on the advice of counsel. (CA Resp. Dey SOF ¶ 36.)

## **ARGUMENT**

### **A. The Government Knowledge Defense Under California Law.**

Plaintiffs' claims arise under the CA FCA, which in pertinent part imposes liability for mandatory treble damages and civil penalties upon any person who "knowingly presents or causes to be presented to an officer or employee of the state . . . , a false claim for payment or approval." (*Id.* at § 12651(a)(1)). The ultimate purpose of the CA FCA is to "protect the public treasury and the taxpayer," and the Act "must be construed broadly to give the widest possible coverage and effect to the prohibitions and remedies it provides. [Citation]." *County of Kern v. Sparks*, 149 Cal. App. 4th 11, 17 (2007); *see also*, CAL. GOV'T CODE § 12655(a) (CA FCA "shall be liberally construed and applied to promote the public interest").

To prove a violation of the CA FCA, the government must establish that (1) a claim was submitted (2) for payment with government funds; (3) the claim was materially false; and (4) the defendant acted "knowingly." *See, generally, Fassberg Constr. Co. v. Housing Auth. of Los Angeles*, 151 Cal. App. 4th 267 (2007); *City of Pomona v. Superior Court*, 89 Cal. App. 4th 793 (2001). The statute defines "knowingly" to include acting: (A) with actual knowledge of the



information, (B) in deliberate ignorance of the truth or falsity of the information, or (C) with reckless disregard of the truth or falsity of the information. CAL. GOV'T CODE § 12650 (b)(2). “Proof of specific intent to defraud is not required.” *Id.*

Notwithstanding the fact that “reliance” on the part of the government is not an element of a false claims action, courts have recognized that knowledge of a claim’s falsity *and* the fully-informed approval of the underlying conduct by an authorized government official may negate the falsity required (and/or vitiate the requisite scienter) under the CA FCA.<sup>2</sup> For example, in *People v. Duz-Mor Diagnostic Lab., Inc.*, 68 Cal. App. 4th 654 (1998), employees of Duz-Mor discussed certain billing problems with a Medi-Cal representative, who advised the lab to “unbundle” its billing for specified tests. The Court of Appeal held that the diagnostic lab’s subsequent actions did not raise a CA FCA claim, in that “Duz-Mor adopted the billing practice at issue here on the instructions of a Medi-Cal representative, and did not knowingly make a false claim.”<sup>3</sup> *Id.* at 672. Similarly, in *Laraway v. Sutro & Co.*, 96 Cal. App. 4th 266 (2002), a Sutro representative engaged in interstate travel on behalf of a school district without obtaining the required school board pre-approval for his travel expenses. With full knowledge of the facts, after the trip school district officials directed Sutro to bill for the expenses it had incurred. The Court of Appeal found no CA FCA claim under such circumstances, holding that “there can be no false claim where a contractor has submitted a claim in accordance with government directions, even if the procedure was improper.” *Id.* at 272.

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<sup>2</sup> Similar standards apply under the Federal FCA. *See, e.g., United States ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542, 545 (7th Cir. 1999)(“If the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a false or fraudulent claim”); *United States ex rel Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991)(“[t]hat the relevant government officials know of the falsity is not in itself a defense”).

<sup>3</sup> The state appellate court further noted that the lab’s unbundled billing practices did not violate the applicable regulation and were at most “an error in billing practices.” *Id.* at 673.

A third instance in which fully informed, authorized government officials approved—indeed, directed—the conduct at issue is found in *American Contract Services v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854 (2001). There, the Department of General Services cancelled a competitive bidding process in order to contract directly with bidder Allied. After Allied performed and was paid, unsuccessful bidder American Contract Services brought a claim under the CA FCA, alleging that Allied’s claim was submitted pursuant to a void contract. The Court of Appeal held otherwise, finding there was no CA FCA claim since the alleged wrongdoing “was known to and initiated by the government.” *Id.* at 865. The appellate court emphasized that where “the government knows and approves of the particulars of a claim for payment before the claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim. In such a case, the government’s knowledge effectively negates the fraud or falsity required by the CFCA.” *Id.* at 864.

Dey falls far short of showing that it is entitled to summary judgment on the basis of its government knowledge defense. To the contrary, as a matter of law, the facts shown by Dey, even if accepted, fail to make out such a defense. Accordingly, Dey’s motion should be denied.

**B. Dey’s Remaining Arguments Do Not Warrant Summary Judgment.**

Dey argues that Medi-Cal could have examined Dey’s reported Wholesale Acquisition Cost prices (“WACs”), and allegedly would have realized that Dey’s AWP’s were grossly inflated. But WAC pricing is not relevant to this case. Medi-Cal did not use WACs and was not required to do so. Dey, moreover, knew that Medi-Cal, like most state Medicaid programs, reimbursed based on AWP. (CA Resp. Dey SOF ¶ 14.) The government, moreover, is not required to piece together the facts as they are selectively disclosed by a Defendant. *See Massachusetts v. Mylan Labs.* (“*Mylan Labs.*”), 608 F. Supp. 2d 127, 152 (D. Mass. 2006)

(defendants can't succeed on government knowledge defense where there was no evidence they ever "disclosed the actual underlying facts," and "even if you didn't need Einsteinian quantitative skills to discover the fraud," state government's failure to do so was not tantamount to knowledge and approval).<sup>4</sup>

As this Court has previously held, evidence of government knowledge concerning an issue "does not support an across-the-board government knowledge defense [where] there is no evidence of government sanction." *Mylan Labs.*, 608 F. Supp. 2d at 151. Furthermore, the case law requires *specific* approval of the *specific* conduct engaged in by the Defendant. To hold otherwise would give defendants *carte blanche* to engage in ongoing schemes by arguing that the government's efforts to investigate and attempt a fix for a defendant's malfeasance itself constitutes knowledge and approval of the underlying unlawful conduct. "[O]penness and honesty are required if government healthcare programs are "not to be turned into a cat and mouse game in which clever providers could, with impunity, practice fraud on the government." *United States v. Calhoun*, 97 F.3d 518, 529 (11th Cir. 1996); *see also Mylan Labs.*, 608 F. Supp. 2d at 148-50 (observing, *inter alia*, that there was no evidence "the Commonwealth knew that the spreads for drugs were almost frequently greater than 50 percent, consistently in the hundreds, and frequently in the thousands"). Here, the pieces of information cited by Dey would not have enabled a government official to knowingly approve Dey's reporting of false prices, and there is no evidence that any government official ever did. According to Dr. Kevin Gorospe, Chief of the Pharmacy Policy Branch of the Medi-Cal Pharmacy Benefits Division, Dey did not inform Medi-Cal that its reported AWP's were grossly inflated:

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<sup>4</sup> Dey attempts to spotlight the fact that a Medi-Cal official, Dr. Gorospe, became aware of the differences between Dey's WACs and its AWP's. But, as Dey is aware, that awareness (which Dey did not affirmatively initiate) occurred in May 2004, at the end of the relevant period and at a time when the California Legislature was already working on a revised reimbursement formula which, in August 2004, increased the AWP discount from minus 10% to minus 17%.

Q. Did Dey ever to your knowledge come to the California Department of Health Care Services and tell the Department that it was reporting grossly inflated Average Wholesale Prices on its drugs?

MR. ROBBEN: Objection as to form.

THE WITNESS: No.

(CA Resp. Dey SOF ¶ 36.)

Dey also argues that various OIG reports advised Medi-Cal of the fact that the AWP's for certain of Dey's products were inflated. But most of these reports relate to Medicare, and Dey has made no showing that Medi-Cal personnel were aware of these reports. In addition, some of the reports consider prices paid by the Veterans Administration to purchase drugs. Medi-Cal is a reimbursement system, not a drug purchaser, so any comparison between the two is not valid.

More fundamentally, Medi-Cal could not use this information. Medi-Cal employed a statutorily defined method to determine the Estimated Acquisition Cost of drug products. Even if Medi-Cal knew the AWP's for certain of Dey's products were generally inflated, it never had a specific understanding of the magnitude of the spreads on Dey's drugs. The appropriate conclusion to draw from the OIG reports is their conveyance of clear *disapproval* of the conduct at issue. As this Court previously noted, OIG's Pharmaceutical Guidelines released in 2003 "defeat any notion that the federal government's failure to change the AWP pricing benchmark signaled acquiescence in spread-marketing or the reporting of mega-spreads." *In re Pharm. Indus. Average Wholesale Price Litig*, 491 F. Supp. 2d 20, 95 (D. Mass. 2007). The same principle is equally applicable to the other OIG reports cited by Dey.

Dey seems determinedly oblivious to the fact that Dey itself ignored the OIG reports. Dey never contacted Medi-Cal, and never expressed any desire to assist in finding a solution to

mitigating the impact of its fraudulently inflated AWP's. As Chief Deputy Director Stan Rosenstein of DHCS confirmed:

Q. I think you were showed earlier in the day an exhibit. I think it was Exhibit 5, a 1996 report by the OIG concerning its examination of the discrepancy between AWP's and acquisition costs for generic and branded drugs. Do you recall that?

A. Yes.

Q. To your knowledge, did any manufacturer come to the Medi-Cal program after the OIG issued that report to offer help in reforming its reporting of AWP's?

A. No.

Q. Did any manufacturer come to the program expressing any concern about the implications of that report to your knowledge?

A. Not to my knowledge, and never to me.

(CA SOAF Dey ¶ 1.)

According to Mr. Rosenstein, reporting accurate prices would have eliminated the need to change the reimbursement formulas and would have resulted in an accurate reimbursement system, saving millions of dollars.

Q. If manufacturers AWP's had been reported by the manufacturers owning those AWP's as actual and accurate measures of their -- of the average wholesale prices of those drugs, would that have affected Medi-Cal's efforts to contain its drug reimbursement costs?

Mr. Bueker: Objection as to form.

A. Yes. We have been -- we spent all day talking about the effort we've had to get accurate pricing. Had we started with accurate pricing, we wouldn't have had to go through all of these changes, and we would have had an accurate reimbursement system in the Medi-Cal program. That would have saved the taxpayers hundreds of millions of dollars.

(CA SOAF Dey ¶ 2.)

Finally, Medi-Cal's failure to adopt the DOJ AWP's did not signal approval of Dey's reporting of inflated AWP's. Although the proposed AWP's were the result of a drug pricing investigation, the attempted change in AWP's was unworkable, and the effort was dropped shortly after it was begun. California did not use the DOJ AWP's because they were believed to be inaccurately low and based on flawed data. Since many of these drugs were administered in doctors' offices, any providers that were inadequately reimbursed would simply stop administering these drugs, causing patients to go to more expensive hospitals for the drugs. (Reid Decl. Ex. 43 at CAAG/DHS0076375.) Second, California's Medi-Cal Drug Program was not structured to work with two sets of AWP's. The new revised AWP's applied only to FFS (fee for service) Medi-Cal patients but not those enrolled in Medi-Cal's managed care program, and the Rebate Program would not function properly if there were two different AWP's used as the cost basis for reimbursement. (*Id.*) Plaintiffs further note that the DOJ AWP's were, at best, a partial and incomplete approach to Medi-Cal reimbursement issues and that the California Legislature had directed the program to perform a comprehensive study of these issues, which was in the preliminary stages.

It is noteworthy that, in spite of Dey's insistence that the government had "knowledge" of its fraudulently inflated AWP's, Dey has never provided accurate AWP's to California. Stan Rosenstein, Chief Deputy Director of Health Care Services, testified that Dey has never revealed the spread on its drugs to California's legislature. And no one in the legislature has ever accepted or approved any inflated or false AWP's.

Q. So to your knowledge, no drug manufacturer, and in particular, no generic drug manufacturer made any effort to come to the California Legislature and explain that actual provider cost are value A and our AWP's are value B, and here is the difference between them?

A. I am not aware of it. Generally, we hear a lot of activity from the legislative staff, have contacts. I am not aware of anybody ever having that contact.

Q. Did you ever hear of any staffer or legislator in either the Senate or the Assembly state an acceptance of inflated AWP's or acceptance of reimbursement from the Medi-Cal program of pharmacy drugs based on inflated or untruthful AWP's?

Mr. Bueker: Objection as to form.

Mr. Cyr: Objection.

A. No, I do not. In fact, I have heard it quite the opposite of strong objection to the government getting false information.

(CA SOAF Dey ¶ 3; *see also*, CA SOAF Dey ¶ 4.)

In short, California did not receive accurate prices, and never approved or ratified the phony prices Dey reported. California never consented to paying at mega-spreads or inflated AWP's. Rather, as Mr. Rosenstein testified, "It has always been our policy to have accurate information and to use that information to establish what the accurate price should be . . . on both ends of the equation." (CA SOAF Dey ¶ 2.) Similarly, it was never Medi-Cal's policy to either overpay or under-reimburse providers for their drug ingredient costs. (CA SOAF Dey ¶ 7.) According to Mr. Rosenstein, "It was never the policy of the department to ever accept false information." (CA SOAF Dey ¶ 6.) And it was not the policy to over-reimburse.

Q. Was there any official policy at Medi-Cal that indicated that Medi-Cal wanted to reimburse significantly above actual acquisition cost?

MR. COLE: Object to the form.

THE WITNESS: Not to my knowledge.

(CA SOAF Dey ¶ 7.) Medi-Cal's reimbursement program was designed to rely upon the prices that manufacturers reported for their drugs. "You know, it is an underlying law and assumption that people, when they interact with the government, are going to tell the truth and provide

accurate information. The entire Medi-Cal program relies upon the honesty of people who participate in the program.” (CA SOAF Dey ¶ 10.)

Dey’s argument boils down to the proposition that, because Medi-Cal continued to reimburse based on reported AWP—pursuant to long established procedures that were mandated by regulation and statute—the State must have “approved” Dey’s reporting of fraudulently inflated AWP. But the failure of a government agency to change a long-established and generally well-functioning system because a small number of companies are taking advantage of that system is hardly surprising, and certainly does not constitute acquiescence in the conduct of those outliers. Rather, the appropriate response is litigation against the wrongdoers, which California is pursuing. Dey’s government knowledge arguments are without merit.

### CONCLUSION

For the above reasons, Plaintiffs respectfully request this Court to deny Dey’s motion for partial summary judgment.

Dated: December 21, 2009

Respectfully submitted,

EDMUND G. BROWN JR.  
Attorney General for the State of California

By: /s/ Rita Hanscom  
NICHOLAS N. PAUL  
Supervising Deputy Attorney General  
RITA HANSCOM  
Deputy Attorney General  
ELIZABETH VOORHIES  
Deputy Attorney General  
Bureau of Medi-Cal Fraud and Elder Abuse  
Office of the Attorney General  
1455 Frazee Road, Suite 315  
San Diego, CA 92108  
Telephone: (619) 688-6026  
Fax: (619) 688-4200



**Attorneys for Plaintiff,  
STATE OF CALIFORNIA**

THE BREEN LAW FIRM, P.A.

By: /s/ James J. Breen  
JAMES J. BREEN  
The Breen Law Firm, P.A.  
5755 North Point Parkway, Suite 260  
Alpharetta, GA 30022  
Telephone: (770) 740-0008

KRAUSE KALFAYAN BENINK & SLAVENS LLP

By: /s/ David Zlotnick  
DAVID ZLOTNICK  
Krause Kalfayan Benink & Slavens, LLP  
625 Broadway, Suite 635  
San Diego, CA, 92101  
Telephone: (619) 232-0331

**Attorneys for Relator,  
VEN-A-CARE OF THE FLORIDA KEYS, INC.**

**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 21, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Rita Hanscom  
RITA HANSCOM